UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	))))	MDL NO. 2272
This Document Relates to the Below Listed Cases	))))	Master Docket Case No. 1:11-cv-05468 Honorable Rebecca Pallmeyer

James Krammes, et al. v. Zimmer, Inc., et al., 1:11-cv-05488
Beverly Goldberg v. Zimmer Holdings, Inc., et al., 1:11-cv-06425
Margaret Loveday, et al. v. Zimmer, Inc., et al., 1:11-cv-05752
Victoria Messina, et al. v. Zimmer, Inc., et al., 1:11-cv-06423
Corda B. Gaddy v. Zimmer, Inc., et al., 1:12-cv-00089

ZIMMER'S REPLY TO
CERTAIN PLAINTIFFS' RESPONSES TO THE
ZIMMER ENTITIES' MOTION FOR SUGGESTION OF REMAND

In the three months since Zimmer[1] filed its Motion For Suggestion Of Remand ("Motion For Remand"), the case for enforcing the boundaries of this MDL has only strengthened. The Judicial Panel on Multidistrict Litigation (the "Panel" or the "JPML") has reiterated and enforced the scope it created for this MDL in its initial Transfer Order, and has stated that Zimmer's position on the scope of the briefing and argument before the Panel, as stated in Zimmer's Motion For Remand, is correct. Six of fourteen Plaintiffs have agreed with

[1] For purposes of this reply, "Zimmer " includes the following defendants: Zimmer, Inc., Zimmer Holdings, Inc., Zimmer Surgical, Inc., f/k/a Zimmer Orthopaedic Surgical Products, Inc., Wilson/Phillips Holdings, Inc., d/b/a Zimmer Wilson/Phillips, Orthopaedic Technologies, LLC, d/b/a Zimmer Tri-State (incorrectly named as (1) Zimmer Tri-State d/b/a Tri-State Orthopaedic, (2) Zimmer Tri-State d/b/a Zimmer, Inc., and/or (3) Zimmer Tri-State d/b/a Tri-State Orthopedic), K. Michael Melia, d/b/a Zimmer Melia & Associates, Inc. (incorrectly named as Zimmer Melia & Associates, Inc.), Zimmer Orthobiologics, Inc., Zimmer US, Inc., and Zimmer Production, Inc.

Zimmer's Motion For Remand and stipulated to remand or dismissed their case outright, and in discovery rulings this Court has generally limited this centralized litigation to the MDL Products.

These developments undermine Plaintiffs' opposition to Zimmer's Motion For Remand. The JPML's Transfer Order stated that this MDL is about the loosening of specific NexGen components. The Transfer Order, and the Panel's subsequent orders and actions are clear that this MDL is not about the NexGen system as a whole. Continued inclusion of cases where the NexGen Femoral Components and the 5950 MIS Tibial Component (the "MDL Products") are not at issue, and thus, there is an absence of common issues, will bog down the MDL not just with discovery on additional products, but discovery on additional experts, theories of defect, and substantive legal claims. Zimmer, therefore, respectfully requests that the Court continue to enforce the boundaries established by the Panel's Transfer Order, and the Panels subsequent orders and actions reaffirming the limitations of this MDL, by entering a Suggestion of Remand for the above listed cases.

I. FACTS

A. The Panel Has Reaffirmed That Scope Of The MDL Includes Only NexGen Flex Femoral Components And 5950 MIS Tibial Components

On April 17, 2012, the JPML entered an order vacating its conditional transfer order as to *Christy Beerbaur v. Zimmer, Inc., et al*. JPML Dkt. 557, attached as Exhibit 1. The Panel stated,

> The record indicates that *Beerbaur* involves a Zimmer knee replacement component outside the defined scope of the MDL . . . . As Zimmer correctly notes, the briefing and oral argument with respect to the initial Section 1407 motion focused on two types of products from the NexGen System – the NexGen Flex Femoral components and the NexGen MIS Tibial component. *See In re: Zimmer NexGen Knee Implant Prods. Liab. Litig.*, 802 F. Supp. 2d 1374, 1376 (J.P.M.L. 2011) (identifying the components at issue as "Zimmer's "high-flex" [NexGen] femoral components (*i.e.*, the Cruciate Retaining (CR) and Legacy Posterior Stabilized (LPS)

> components, and the "Gender Solutions" versions thereof) and/or the MIS Tibial component").

Exhibit 1. In this order, the Panel specifically stated that the scope of the MDL involves only specific *components* and explicitly distinguished the individual components from the NexGen *System*. *Id*.

The Panel's recent actions in *Magruder v. Zimmer, Inc., et al.* and *Pace v. Zimmer, Inc., et al.* further highlight the distinction between the NexGen "system," and even the NexGen Flex "system," and the *specific components* at issue in this MDL. In *Magruder* and *Pace*, the Plaintiffs alleged that their cases involved the failure of a "Zimmer NexGen High Flex knee replacement system." Complaints, at 1, attached as Exhibit 2. The Clerk of the Panel required the parties to inform the Panel of the "specific Zimmer knee *components* [] at issue in the actions." JPML Dkt. 508, attached as Exhibit 3 (emphasis added). Again, the Panel found that a statement that a case involves a NexGen Flex *system* is insufficient to merit its inclusion in the MDL.

Magruder and *Pace* are not the only examples of the Panel's continuing careful scrutiny of the scope of this MDL. Since Zimmer filed its Motion to Transfer, the Panel has requested supplemental information in a total of four cases. *See* JPML Dkt. 382, 605 attached as Exhibit 4.

B. <u>Six of Fourteen Plaintiffs Have Stipulated to Remand</u>

Since Zimmer filed its Motion For Remand, almost one half of the Plaintiffs with cases at issue have agreed with Zimmer that their cases are outside of the scope of the MDL. Those Plaintiffs have either filed stipulations to the Motion For Remand or dismissed their case outright. Those cases and their stipulations can be found at:

Case Name	NDIL Cause Number	Docket Number
Frances Beaman v. Zimmer, Inc., et al.	1:11-cv-07547	11-cv-5486, DN 372
Cheryl Gustafson, et al. v. Zimmer, Inc., et al.	1:11-cv-05746	11-cv-5486, DN 247
Anita McCants, et al. v. Zimmer, Inc., et al.	1:11-cv-05757	11-cv-5486, DN 248
David R. Langevin v. Zimmer, Inc., et al.	1:11-cv-05476	11-cv-5486, DN 254
Elsie Alice Buehler v. Zimmer, Inc., et al.	1:11-cv-05749	11-cv-5749, DN 8
Patricia Monroe v. Zimmer, Inc., et al.	1:11-cv-05734	11-cv-5486, DN 366

Plaintiffs in three other cases, *Carr, Quade, and Waterman*, provided additional facts regarding their revision surgeries or their medical history, which led Zimmer to withdraw its Motion For Remand as to those cases. Dkt. 478. Zimmer's withdrawal of its motion as to these cases is based solely on plaintiff-specific factual issues Zimmer learned after filing its Motion For Transfer.

Accordingly, only five cases remain at issue.[2] One is the *Krammes* case, which involves neither a Flex Femoral Component nor a 5950 MIS Tibial Component. The remaining four, *Loveday, Messina, Goldberg, and Gaddy,* involve a non-5950 MIS Tibial Component and a Flex Femoral Component, *none of which has loosened or failed.*

[2] Zimmer's reply is therefore limited as to the three responses filed by these five Plaintiffs and the Plaintiffs' Steering Committee:

1) Plaintiffs' Steering Committee's Omnibus Memorandum In Opposition To Defendants Zimmer Entities' Motion For Suggestion Of Remand, Dkt. 374;
2) Plaintiffs Margaret Loveday and Victoria Messinas' Opposition To Zimmer Entities' Motion For Suggestion Of Remand, Dkt. 417; and
3) Plaintiffs, James And Deborah Krammes, Response to Zimmer Entities' Motion For Suggestion Of Remand, Dkt. 370.

Plaintiff Beverly Goldberg also filed a response in opposition. Dkt. 379. That response, however, was solely a notice that Goldberg adopts the Plaintiffs' Steering Committee's response. Zimmer also responds to Ms. Goldberg's response in this reply.

C. The Court Has Generally Limited Discovery Of Tibial Components To The 5950 MIS Tibial Component

On February 7, 2012, Zimmer filed a Motion for Protective Order to limit the scope of discovery in the MDL to the MDL Products. Dkt. 231 – 32. One of the disputes between Plaintiffs and Zimmer was the scope of discovery on tibial components. Plaintiffs' arguments in their opposition to the motion, Dkt. 245, and before the court at the February 24 and April 12 status conferences were remarkably similar to the arguments they have made in opposition to Zimmer's Motion For Remand. Plaintiffs' arguments in opposition found in both the briefing on the protective order and the briefing on the Motion For Remand include, (1) that Zimmer has misinterpreted the briefing and argument before the JPML; (2) the JPML's Transfer Order should be interpreted more broadly; (3) that the NexGen knee is a family of interchangeable parts and that tibial components are interchangeable with NexGen Flex Femoral Components; (4) that the design of the Flex Femoral Component can cause chain failure of the tibial components; and (5) that Zimmer's MIS common surgical technique and instruments somehow justify broadening the scope of this MDL.[3]

In the face of these arguments, on the understanding that the 5950 is the only tibial component properly in this case, the Court granted Zimmer's Motion For Protective Order, in part. Transcript of April 12, 2012, Status Conference, 32:11-19 attached as Exhibit 5. Dkt. 413.

[3] This issue has been repeatedly briefed before the Court, including in Zimmer's Motion For Remand (Dkt. 237); Plaintiffs' various briefs in response (*See* n.2, above); Zimmer's Motion for Protective Order (Dkt. 231); Plaintiffs' response (Dkt. 245); and Zimmer's reply thereto (Dkt. 250); and in motions and other argument before the Court including those on the scope of the short form complaint and the scope of discovery. Zimmer respectfully references and incorporates its previous statements, citations, and quotations on the pleadings and argument before the JPML to the extent it wishes to consider them in this reply.

II. CASES WITHOUT A LOOSENED FLEX FEMORAL COMPONENT OR 5950 MIS TIBIAL COMPONENT SHOULD BE REMANDED

The outstanding issue on four of the five remaining cases is whether the loosening of a non-5950 tibial component, where no other component of a plaintiff's knee replacement has loosened, is a sufficient basis for a case to remain centralized in this MDL. The Plaintiffs have repeatedly attempted to expand the scope of this MDL to tibial components beyond the 5950 MIS Tibial Component. Just as the Court did in the context of the Protective Order and the Panel did in its Transfer Order and subsequent actions in the *Beerbaur*, *Pace* and *Magruder* cases, the Court should continue to limit this MDL to cases where a Flex Femoral component or a 5950 MIS Tibial Component loosened or failed.

A. This MDL Is Limited To Specific Components

Both in their initial motion to transfer before the JPML and in their responses to Zimmer's opposition to the creation of the MDL Plaintiffs limited their claims to loosening of specific NexGen components. *See, e.g.*, Zimmer's Reply Memorandum In Support Of Motion For A Protective Order, Dkt. 250, at 1-2. After briefing and argument, the Panel entered an Order describing the common issues as whether "Zimmer 'high-flex' femoral components (. . .) and/or the MIS Tibial Component – . . . – are prone to premature loosening." (emphasis supplied). JPML Dkt. 110 at 2, attached as Exhibit 6. The JPML has now reiterated that position in a *second* order. JPML Dkt. 557 at 1, attached as Exhibit 1. In its more recent order, the Panel stated, "As Zimmer correctly notes, the briefing and oral argument with respect to the initial Section 1407 motion focused on two types of *products* from the NexGen *System* – the NexGen flex femoral *components* and the NexGen MIS Tibial *component*." Exhibit 1 (emphasis added, citation omitted). Here, the JPML reinforces the plain statement of its Transfer Order,

and makes clear that this MDL is limited to loosening of specific components. Moreover, it again distinguishes those specific components from the NexGen System as a whole.

Loosening of the MDL components themselves is at the heart of the JPML's Transfer Order. The JPML makes no reference to any claim that the specific MDL components cause the loosening of other knee replacement components. To the contrary, it stated that the common factual issues were the premature loosening of these specific components. Exhibit 6, at 1-2 (quoted at pages 2-3, above). The Panel has followed up on its words of limitation with action. As the Panel's requests for supplemental information in *Magruder* and *Pace* have shown, stating that a case involves a "Zimmer NexGen High Flex knee replacement system" is insufficient for the Panel to transfer a case to this MDL. When presented with a general "system" claim such as in *Magruder* and *Pace*, the first step the panel takes is to request information on the "specific Zimmer knee *components* [] at issue in the action." Dkt. 508, attached as Exhibit 3 (emphasis added).

In fact, the very scientific articles on which Plaintiffs found their case show no impact on tibial components. Plaintiffs have relied heavily on a 2007 study performed by Han et al., titled *High incidence of loosening of the femoral component in legacy posterior stabilized-flex total knee replacement*, 89-B J. BONE JOINT SURG. [BR] 1457 (2007). Master Long Form Complaint, Dkt. 211, at 28. That study specifically noted that in all knee replacement surgeries analyzed, "[n]o knee showed loosening or osteolysis associated with the patellar and tibial component." *Id.* at 1458-59. Plaintiffs have also relied on a study performed by Cho et al., titled *Three- to six-year follow-up results after high-flexion total knee arthroplasty: can we allow passive deep knee bending?*, 19 KNEE SURG SPORTS TRAUMATOL ARTHROSC 899 (2011). *Id.* at 28-29. That study, which evaluated 218 knee replacements in 166 patients, found that with

respect to loosening, "[o]nly femoral components were involved." *Id.* at 900-901. The study noted no loosening of tibial or patellar components. *See id.*

Plaintiffs' own authorities thus contradict their post-JPML theory that flex femoral components somehow cause non-5950 tibial components to loosen.

The JPML has limited the scope of this MDL to the specific MDL Products, and the Court should not expand the scope of the MDL by allowing cases whose focus is the loosening or failure of non-MDL Products to remain centralized.

B. Limiting The MDL To The Relevant Products Will Ensure Efficiency

The continued inclusion of four cases where the only product that has loosened or failed is not an MDL Product will threaten the efficient progress of the over 400 cases already centralized in the MDL. As detailed in Zimmer's Motion For Remand, inclusion of these cases will necessitate additional product discovery, expert discovery, and discovery regarding varying theories of defect. Dkt. 237, at 7-8. These cases will consume judicial resources somewhere, either in this Court or in a district court elsewhere. Because they would only serve to expand the scope of an already massive piece of litigation while being such a small piece of that litigation, they will be more efficiently litigated as individual cases.

The plaintiffs' own medical records reveal the lack of common issues. As detailed in Zimmer's Motion For Remand, in all four cases at issue, the plaintiffs had a revision surgery. Even though the plaintiff was having a second knee operation, each of their surgeons chose not to remove the MDL Product they received and the Plaintiffs continue to have the MDL Products implanted to date. Dkt. 237, at 17-22. These cases therefore, are very different than the other of the cases in this MDL, and these differences will lead to additional and distinct fact discovery, expert discovery, and motions practice.

The steady march of this MDL, as directed by both the JPML and the Court, has been toward focusing the litigation on the MDL Products. In word and deed, the JPML has repeatedly confirmed that this MDL is limited to specific components and that allegations regarding knee "systems" are insufficient to centralize an action with this MDL. Over the objections of Plaintiffs and arguments essentially identical to those made in the opposition to Zimmer's Motion For Remand, this Court has generally limited written discovery of Zimmer to the MDL Products. The four cases remaining at issue here[4], where no MDL Product loosened or failed, should not continue to be centralized in this MDL. Their continued inclusion is outside the scope of the MDL ordered by the JPML, outside the scope contemplated by the Court's recent discovery orders and, as detailed in Zimmer's Motion For Remand, would invite inclusion of other cases outside the scope of this MDL and threaten a substantial expansion of the scope of this MDL. Zimmer, therefore, respectfully requests that Court file a Suggestion with the JPML that *Goldberg*, *Loveday*, *Messina* and *Gaddy* should be remanded to their originating jurisdiction.

III. KRAMMES SHOULD BE REMANDED

Krammes involves no MDL Component: neither a NexGen Flex Femoral Component nor a 5950 MIS Tibial Component. Instead it involves a 5954 Trabecular Metal Tibial Tray, a different type of tibial component, with pegs instead of the 5950's keel and stem, and trabecular metal for uncemented use as opposed to the cemented 5950. To the best of Zimmer's knowledge, Mr. Krammes' tibial component was part of a limited lot, manufacturing recall. Mr. Krammes has alleged that his tibial tray failed for the same reason the product was recalled: the trabecular metal coating on the tray may become separated from the titanium body of the device. Brief In Support of Plaintiffs, James And Deborah Krammes, Response to

[4] Again, *Loveday*, *Messina*, *Goldberg*, and *Gaddy*.

Defendants' Motion For Suggestion Of Remand, Dkt. 371, at 3. The theory of defect and causation for Mr. Krammes' claims are completely different than any allegations raised with respect any other MDL Products, and it should not be centralized with this MDL.

Krammes makes three arguments in opposition to Zimmer Motion For Remand: (1) that the tibial plate at issue in his case is part of a "unified knee replacement system," (2) that the JPML's Transfer Order is not as narrow as Zimmer argues, and (3) that the MIS surgical technique and instruments, which may not have even been used in Mr. Krammes' implant surgery, provides sufficient commonality to the MDL to justify continued centralization. Zimmer has already extensively addressed the first two arguments in section III.A, above, with regard to cases with flex femoral components. Krammes' argument is even more tenuous as *none* of his components are MDL Products.

As to Krammes' third argument, this case was specifically raised at the most recent status conference on April 12, 2011, in a larger discussion regarding discovery on all MIS tibial components generally. Tr. 33:18 – 45:14, attached as Exhibit 5. As previously discussed, the Court rejected Plaintiffs' argument that discovery should go to all MIS tibial components on the theory that the common MIS surgical technique and instruments merit the expansion of the scope of the MDL. Instead the Court generally limited the scope of written discovery to Zimmer regarding tibial components to the 5950.

As the Krammes case has no connection to this MDL, Zimmer respectfully requests that the Court file a Suggestion with the JPML that the Panel remand to the case to its originating jurisdiction.

Dated: May 14, 2012

Respectfully submitted,

FAEGRE BAKER DANIELS LLP

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CERTIFICATE OF SERVICE

I certify that on May 14, 2012, a copy of the foregoing Zimmer's Reply To Certain Plaintiffs' Responses To The Zimmer Entities' Motion For Suggestion Of Remand was filed electronically. Parties may access this filing through the Court's system.

/s/ Joseph H. Yeager, Jr.